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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/647,777 | 12/29/2000 | Hiroyuki Morimoto | 2500.6 | 3913 |

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EXAMINER

TRAN, SUSAN T

ART UNIT PAPER NUMBER

1615

DATE MAILED: 04/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|--------------------------------------|--|--|
| Office Action Summary | Application No. 09/647,777 | Applicant(s) MORIMOTO ET AL. | |
| | Examiner Susan T. Tran | Art Unit 1615 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 January 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 42-53, 63-70 and 72-79 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 42-53, 63-70 and 72-79 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 01/31/06 has been entered.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 42-53, 63-70 and 72-79 are rejected under 35 U.S.C. 103(a) as being unpatentable over Morimoto et al. EP 0 650 826 A1, in view of Roche US 5,075,114.

Morimoto teaches a tablet compressing method using tableting machine with lubricant spraying mean (see abstract). The method comprising spraying lubricant uniformly on the surface of an upper punch, a lower punch, and a die, filling the die with pharmaceutical materials, and compressing the pharmaceutical material to form a drug tablet (columns 2-3 and columns 5-7).

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Morimoto does not teach the specific form of pharmaceutical material being claimed, such as, coated granule or granule in a matrix base. Nonetheless, Morimoto teaches that his tableting method can be used for tableting many kinds of tablets such as powdered or granular medicine, and so on (column 7, lines 34-38).

Roche teaches a medicament tablet comprising granules coated with polymers blend (see abstract and column 2, lines 45-60). The resulting coated granules were then compressed into tablet form using tableting machine having die wall and punches (columns 9-10). Thus, it would have been obvious for one of ordinary skill in the art to modify the pharmaceutical materials to be tableted in Morimoto using the coated drug granule in view of the teaching of Roche, because the references teach the use of compressed tableting machine to compress pharmaceutical materials.

Claims 42-53, 63-70 and 72-79 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leal et al. US 3,042,531, in view of Tuerck et al. US 3,084,104.

Leal teaches a method of making a compressed tablet comprising applying a minute amount of die-lubricant to all the tablet-contacting surfaces of the die, introducing product composition devoid of lubricant into this same die, and compressing the pharmaceutical material to form a tablet (column 2, lines 46-71).

Leal does not expressly teach the claimed pharmaceutical compressed material, such as, coated granule or granule in a matrix base.

Tuerck teaches coated medicinal agent to form coated active particles, and compressed the coated active particles to tablet (column 1, lines 64 through column 3,

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lines 1-19). Thus, it would have been obvious for one of ordinary skill in the art to modify the pharmaceutical materials to be tableted of Leal using the coated drug particles in view of the teaching of Tuerck, because Leal teaches a tableting method suitable for any tablet composition no matter how difficult to tablet (column 2, lines 21-24), because Leal teaches a tableting method that enables tablets of a wide range of hardness or softness to be produced without objectionable fracturing or other damage (column 4, lines 41-48), and because Tuerck teaches coated active particles suitable for compressed tablet (column 1, lines 8-34).

Claims 42-53, 63-70 and 72-79 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tsushima et al. US 6,036,974, in view of Roche US 5,075,114.

Tsushima teaches a method for preparation of tablet comprises preparing the tableting material containing medicines and excipients, coating on the surface of the tableting material a lubricant, coating the surface of the punches with lubricant, filling the die with the coated tableting material, and compressing to obtain tablet (columns 2 and 6).

Tsushima does not teach the specific form of pharmaceutical material being claimed, such as, coated granule in a matrix base.

Roche teaches a medicament tablet comprising granules coated with polymers blend (see abstract and column 2, lines 45-60). The resulting coated granules were then compressed into tablet form using tableting machine having die wall and punches (columns 9-10). Thus, it would have been obvious for one of ordinary skill in the art to

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modify the tableting materials of Tsushima using the coated drug granule in view of the teaching of Roche, because the references teach the use of compressed tableting machine to compress pharmaceutical materials.

It is noted that the reference is silent as to the teaching of the percent amount of lubricant being coated onto the surface of the die and punches. However, generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Thus, it would have been obvious for one of ordinary skill in the art to, by routine experimentation determine a suitable amount of lubricant to obtain a smooth surface tablet. As well as the dividing line on the tablet, it would have been obvious for one of ordinary skill in the art, because dividing line, groove line, marking line, or scored tablet is well known in pharmaceutical art. Moreover, absent of evident on the contrary, the burden is shifted to applicant to provide data showing the amount of surfactant uses by the cited references do not fall within the claimed range.

Response to Arguments

Applicant's arguments filed 01/31/06 have been fully considered but they are not persuasive.

Applicant argues that Morimoto does not disclose that the tableting granules would not be damaged. In response to applicant's argument that the reference does show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., granules would not be damaged) is not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Even assuming that the feature has been recited in the claims, it is not necessary for the prior art to show each and every property of the claimed product *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). The evidence submitted is insufficient to establish unexpected results over the cited references. Applicant states that the tablet achieved by the present invention is superior in its rapid disintegrability comparing to the tablets described in the cited references. However, table 2 of applicant's specification at page 50 discloses disintegration time of the claimed tablet is 6.0 minute comparing to the comparison example of 10.2 minutes. Applicant's attention is called to the cited references, for example, Tsushima at table 2, column 10, discloses a disintegration time of 0.6 minutes. Applicant also states that table 3 of applicant's specification shows that the tablet of the claimed invention is harder than the tablet of Roche and Morimoto at the same pressure. However, it is noted that the tablet hardness, as well as the specific tableting pressure as disclosed in table 3 are not require in the claims. Applicant also argues that tables 4 and 5 of the specification show unexpected sustained release profile compared to Morimoto's. However, the sustained release profile is not being claimed.

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Applicant argues that Morimoto does not disclose tableting applicants' granules in which active substance is coated with film or granules including active substance in a base matrix. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Morimoto is cited in combination with Roche for the teaching of tableting coated active granule.

Applicant argues that even if Morimoto and Roche are combined, there is no teaching or suggestion to exclude lubricant from the molding material. More importantly, there is no suggestion or expectation that lubricant is applied only on the die and punch surfaces, and a sufficiently hard tablet can be obtained without destroying the granule. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., lubricant is applied only on the die and punch surfaces) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Applicant has not provide data comparing the unexpected results obtained from the claimed invention to that taught by Morimoto.

Pertinent Arts

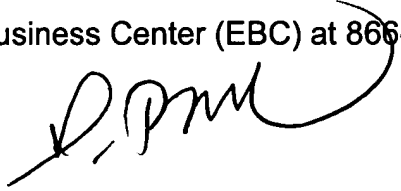
The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Sebastiani, and Doepel are cited as of interest for the teachings of coating the punches and dies of the compressed tablet apparatus.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan T. Tran whose telephone number is (571) 272-0606. The examiner can normally be reached on M-R from 6:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page, can be reached at (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



S. Tran
Patent Examiner
AU 1615